Re-evaluation Note REV2012-08

Chloropicrin, Dazomet, Metam Sodium and Metam Potassium

Label Improvements for Soil Fumigant Products

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Executive Summary

The purpose of this document is to notify registrants, pesticide regulatory officials, and the Canadian public of the re-evaluation status for the active ingredients chloropicrin, dazomet, metam sodium and metam potassium, and of label improvements for the soil fumigant products containing these active ingredients.

This Re-evaluation Note summarizes comments made to the PMRA in response to the Re-evaluation Note documents REV2010-10, *Soil Fumigants Proposed Mitigation Measures*, REV2010-12, *Chloropicrin – Proposed Mitigation Measures*, REV2010-13, *Dazomet – Proposed Mitigation Measures*, and REV2010-09, *Metam Sodium and Metam Potassium – Proposed Mitigation Measures*, published on 13 August 2010. This Re-evaluation Note also provides the PMRA's responses to the comments received.

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Background

Chloropicrin, dazomet, metam sodium and metam potassium are active ingredients under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). These four active ingredients are being re-evaluated concurrently as part of a soil fumigant cluster. Soil fumigants are used to control soil pests or pathogens such as insects, nematodes, bacteria, fungi and weeds, which can disrupt plant growth and production. A fumigant is a volatile chemical that becomes a gas at relatively low temperatures (for example, chloropicrin), or a chemical that reacts to form a gas (for example, dazomet, metam sodium and metam potassium are converted to the active form, methyl isothiocyanate or MITC). In Canada, chloropicrin, dazomet, metam sodium and metam potassium are registered as pre-plant soil fumigants for use on a variety of terrestrial and/or greenhouse food/feed and non-food/non-feed crops, forests/woodlots, ornamentals, nurseries, seed beds and/or turf. The fumigants are applied and incorporated into the soil; treated soil is then sealed and subsequently aerated prior to planting. These active ingredients are also registered as antimicrobials, either as remedial wood preservatives (for example, structural timber) or as preservatives in industrial process fluids (for example, pulp and paper mills, water cooling towers). All currently registered uses are being considered in the re-evaluation.

The regulatory approach and proposed label improvements for the soil fumigant cluster (including antimicrobial uses for these products) were first presented in Re-evaluation Note REV2010-10, *Soil Fumigants Proposed Mitigation Measures*, REV2010-12, *Chloropicrin – Proposed Mitigation Measures*, REV2010-13, *Dazomet – Proposed Mitigation Measures*, and REV2010-09, *Metam Sodium and Metam Potassium – Proposed Mitigation Measures*, published on 13 August 2010. This Re-evaluation Note describes this stage of PMRA's regulatory process for the re-evaluation of the soil fumigant products containing these active ingredients, as well as summarizes the Agency's decision and the reasons for it. The regulatory process for the re-evaluation of antimicrobial products containing chloropicrin, dazomet, metam sodium or metam potassium is communicated in Re-evaluation Note REV2012-07, *Chloropicrin, Dazomet, Metam Sodium and Metam Potassium Label Improvements for Antimicrobial Products*. The comments pertaining to soil fumigants received during the consultation process resulted in some changes to the proposed label improvements as described in the consultation documents. The PMRA also considered any incident reported to date to the PMRA for these active ingredients. Appendix I summarizes the comments received during the consultation and provides the PMRA's response to these comments.

Regulatory Strategy

The PMRA's re-evaluation of the soil fumigant cluster is ongoing. At this time, the PMRA is requiring label improvements to further limit user exposure and further protect bystanders and the environment. These label improvements are considered a first step in the re-evaluation of the Canadian uses of the products containing these active ingredients.

A key component of the label improvements for soil fumigant products containing chloropicrin, dazomet, metam sodium or metam potassium is the requirement of a Fumigation Management Plan (FMP) for all applications. A Fumigation Management Plan is an organized, written description of the required steps involved to help ensure a safe and effective fumigation. It will also assist in complying with pesticide product label requirements. Instructions for the preparation of a Fumigation Management Plan are required to be part of the product label. In addition, a Fumigation Management Plan template will be developed by the PMRA in consultation with registrants in order to help users meet the Fumigation Management Plan requirements. Chemical-specific label improvements are also required for all registered uses. Please refer to Re-evaluation Notes for chloropicrin (REV2012-09 *Label Amendments for Soil Fumigants Products Containing Chloropicrin*), dazomet (REV2012-10 *Label Amendments for Soil Fumigant Products Containing Dazomet*), and metam sodium/metam potassium (REV2012-11 *Label Amendmens for Soil Fumigant Products Containing Metam Sodium of Metam Potassium*) for a full description of the required amendments.

Additional Information

Any person may file a notice of objection[1] regarding this decision for chloropicrin, dazomet, metam sodium and metam potassium within 60 days from the date of publication of this Re-evaluation Note. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) at www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd or contact the PMRA's Pest Management Information Service.

PMRA documents can be found on the Pesticides and Pest Management portion of Health Canada's website. PMRA documents are also available through the Pest Management Information Service.

[1] As per subsection 35(1) of the *Pest Control Products Act.*

Appendix I Comments and Responses

1. Comments on the Regulatory Approach

1.1 Comments pertaining to the value

1.1.1 Comments regarding the value of the active ingredients re-evaluated as part of the soil fumigant cluster were received from various stakeholders. Comments emphasized that soil fumigants are economically important pest management tools for the production of several crops in Canada. Comments also emphasized that fumigation has reduced the need to apply other types of pesticides in many crop production systems.

Response

The PMRA acknowledges that soil fumigants are an important tool for the control of soil pests and pathogens in Canada.

1.1.2 Canadian growers have become very dependent on the remaining soil fumigant products because of the loss of methyl bromide, Telone and Vorlex.

Response

The PMRA recognises the importance of the soil fumigants as a key pest management tool for Canadian growers. The phase-out of methyl bromide, as well as the voluntary withdrawal of the Telone and Vorlex products from the Canadian market, are expected to increase growers' reliance on chloropicrin, dazomet, metam sodium and metam potassium. The anticipated increase in use of these soil fumigant products further emphasizes the need to bring labels for these products up to current standards. As a first step in the re-evaluation of the soil fumigant cluster, the PMRA is implementing label improvements to modernize the labels and normalize fumigation practices across the active ingredients. The label improvements are intended to limit user exposure and to further protect bystanders and the environment. No soil fumigant uses or products are being lost as part of this phase of the re-evaluation.

These label improvements are consistent with measures adopted by the United States Environmental Protection Agency (USEPA). The PMRA continues to monitor the regulatory status of the soil fumigants in the United States and may re-assess the soil fumigant cluster as required.

1.2 Comments on the use of soil fumigants in Canada

1.2.1 History of safe use in Canada

There is no evidence that current soil fumigant application practices or label requirements have caused any problems for the users, workers, bystanders, the general population or the environment to warrant implementation of the proposed mitigation measures. The PMRA should provide additional information to stakeholders on the nature of the concerns that triggered the new measures.

Response

The PMRA recognises the excellent grower and registrant-lead stewardship and training initiatives that have contributed to the predominantly safe and efficient use of the soil fumigants in Canada. However, despite the advances in awareness and application methodology, the PMRA believes that concerns for exposure to users, bystanders and the environment remain. Given the inherent toxicity and irritant properties of the active ingredients, and the potential for both direct and indirect exposure, the PMRA believes that additional measures are warranted to further protect human health and the environment. As a first step in the re-evaluation of the soil fumigant cluster, the PMRA is implementing label improvements to bring the labels up to current standards.

1.2.2 Use practices of the soil fumigants in Canada

In addition to comments on the proposed regulatory actions and mitigation measures for the soil fumigant cluster, the PMRA also received input from growers, grower organizations, applicators, provincial agencies and registrants on the typical soil fumigation use practices in Canada including application equipment, application timing and critical use crops.

Response

The PMRA has reviewed all information that was provided on the use of soil fumigants in Canada. Where required, additional consultation was conducted with provincial application specialists to confirm and elucidate the information further. Changes to the label amendments have been incorporated as necessary to better reflect use of individual active ingredients, and the use of soil fumigants in general in Canada.

1.3 Comment on the suitability of the USEPA Evaluation

The soils in Canada are generally cooler and retain more moisture compared to soils in the United States. This reduces the degree of fumigant off-gassing from soil and can affect the virulence of certain diseases. Furthermore, the fumigation window in Canada is very narrow. It is recommended that the PMRA consider soil characteristics in Canada when implementing the soil fumigant re-evaluation decision.

Response

As a first step in the re-evaluation of the soil fumigant cluster, the PMRA is implementing label improvements to modernize the labels and increase consistency in fumigation practices across the active ingredients. The label improvements are consistent with risk mitigation measures placed on soil fumigants in the United States and are intended to limit user exposure and to further protect bystanders and the environment. Overall, the Canadian use pattern is encompassed by the assumptions used in the USEPA assessments. Field volatility studies from multiple locations in the United States (i.e. California,

Florida, Washington and Michigan) were considered in the USEPA assessments. Conditions observed in the U.S. field volatility studies (for example, soil moisture, soil temperature, etc.) are expected to be conservative to the conditions that can be observed in Canada during the spring season. As such, the PMRA has determined that the risk mitigation measures required in the United States are applicable to the Canadian situation.

2. Comments on the Implementation of the Regulatory Action

2.1 Comment on the Training and Certification Requirements

The proposed mitigation measures require an appropriate pesticide applicator certificate or license recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur. Additional information should be provided outlining the specific provincial training requirements for a soil fumigant applicator certification or license.

Response

Pesticide applicator training and/or certification is the jurisdiction of the applicable provincial/territorial regulatory agency. The training requirements for soil fumigant applicator certification are to be determined by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur. Users should consult the provincial/territorial regulatory agency where the application is to occur for additional information on the specific requirements for obtaining a soil fumigant applicator certificate or license.

2.2 Comment on Product Stewardship Programs

In addition to provincial training in specific areas, the chloropicrin registrant and/or distributor have also trained all applicators that apply these products in Quebec, New Brunswick, and Nova Scotia. The registrant and distributor provide product stewardship through on-site applicator service, calibration, and additional site-specific safety training utilizing experienced set-up and service technicians at no cost to the grower. Clarifications are required as to why additional expensive measures are required.

Response

The PMRA is aware of the registrant-led stewardship and training initiatives that have been put in place for chloropicrin products in Canada. However, product stewardship programs are not in place for all the active ingredients re-evaluated as part of the soil fumigant cluster. Furthermore, despite the advances in awareness and application methodology, the PMRA believes that concerns for exposure to users, bystanders and the environment remain. Given the inherent toxicity and irritant properties of the active ingredients, and the potential for both direct and indirect exposure, the PMRA believes that additional measures are warranted to further protect human health and the environment.

2.3 Comments on the Implementation Timeline

2.3.1 Time frame for implementation

The timeframe for implementation of the soil fumigant re-evaluation decision should be adequate to allow growers time to explore and adopt alternative practices.

Response

The label improvements required by the PMRA have not resulted in the loss of any uses of soil fumigant products currently registered in Canada. The timeline for the implementation of the new requirements will be consistent with standard timelines for re-evaluation.

2.3.2 Transition strategy

A transition strategy should be developed to register reduced-risk soil fumigation alternatives in Canada and implement training programs for growers, applicators and enforcement personnel to understand the new measures.

Response

While the PMRA encourages the development and registration of reduced-risk pesticides in Canada, the label improvements required by the PMRA have not resulted in the loss of any uses or soil fumigant products currently registered in Canada. Therefore, a transition strategy will not be developed for soil fumigants at this time. The PMRA will work with provincial/territorial authorities to ensure certification and training material are revised, when necessary, to reflect the new requirements, and to ensure that the new requirements are adequately communicated to growers, applicators and enforcement personnel.

2.3.3 Alternatives

Registration of reduced risk alternatives to the current soil fumigants should be explored in Canada.

Response

The PMRA encourages the development and registration of reduced risk pesticides and has processes in place to help facilitate access to those products when available.

3. Comments on the Proposed Mitigation Measures

3.1 Comment on the cost of the proposed measures

The implementation of the proposed measures will result in increased production costs for growers, making it more difficult for Canadian produce to compete in the marketplace with produce grown in other countries.

Response

The PMRA recognises that some of the requirements may result in increased production costs. However, given the inherent toxicity and irritant properties of soil fumigants, and the potential for both direct and indirect exposure, the PMRA believes that label improvements are warranted to further protect human health and the environment. These label improvements are consistent with risk mitigation measures placed on soil fumigants in the United States.

3.2 Comments on Application Instructions

3.2.1 Reduced application rates

The proposed mitigation measures include reduced application rates for dazomet, metam sodium and metam potassium uses. The PMRA should include in the decision document a review of available efficacy data to demonstrate the need for and effectiveness of the reduced application rates.

Response

A reduction in maximum application rate was required in the United States, for soil fumigant uses of chloropicrin, dazomet, metam sodium and metam potassium, to more accurately reflect the rates which are currently being used. Buffer zone distances were then determined for the revised rates.

In Canada, buffer zone distances are based on the US buffer zone look-up tables where application rates are expressed in terms of broadcast equivalent rate. The proposed rate reductions for dazomet, metam sodium and metam potassium were meant to reflect the maximum broadcast equivalent rates outlined in the buffer zone look-up tables. The decision document has been modified to clarify this. As such, the PMRA is not reducing the maximum application rates below currently permitted use rate ranges.

3.2.2 Crops listed on label

Soil fumigant products registered for pre-plant application should not be required to list specific crops permitted to be planted after fumigation on the label.

Response

The PMRA agrees that pre-plant applications of soil fumigants do not require that specific crops be listed; label amendments were adjusted accordingly.

3.2.3 Use of handheld equipment

The proposed mitigation measures prohibit use of handheld equipment for the application of dazomet in Canada. Application of dazomet granules using hand-held equipment is important for Canadian growers and should be maintained.

Response

The PMRA has determined that prohibiting the use of handheld application equipment for dazomet is not required in Canada. The USEPA RED requirement for amended dazomet labels to prohibit the use of handheld application equipment was based on the registrant electing to not support this application method. However, based on the revised personal protective equipment requirements for dazomet (for example, handlers are required to wear double layer clothing, boots, chemical-resistant gloves, protective eyewear and (in certain circumstances) a respirator), the PMRA considers that there is adequate protection for handlers applying dazomet using handheld application equipment. The dazomet label amendments have been revised to allow for the continued use of handheld equipment.

3.2.4 Improved application system

The PMRA should take into consideration chloropicrin application systems used in Canada. Chloropicrin is delivered to farms or application sites in Transport Canada approved returnable steel containers. The delivery tank is mounted directly on the tractor or applicator; it is then pressurized with nitrogen gas, and the fumigant is injected under the soil. The majority of Canadian applications have soil bedded up over the injection slit to reduce fumigant escape. There is no fumigant transfer, no container disposal, no fumigant remaining on farm after the application season, and a closed system of fumigant delivery to the target. Growers receive credit for unused fumigant so there is no incentive to keep fumigant on the farm during the off season. This system significantly reduces applicator/handler exposure.

Response

The PMRA recognises the excellent registrant-led stewardship initiatives that have contributed to the predominantly safe and efficient use of chloropicrin in Canada. However, despite the advances in application methodology, the PMRA believes that concerns for exposure to users, bystanders and the environment remain. Given the inherent toxicity and irritant properties of chloropicrin, and the potential for both direct and indirect exposure, the PMRA believes that label improvements are warranted to further protect human health and the environment.

3.2.5 Development of new application methods

The PMRA should work with stakeholders to develop alternative methods such as drip irrigation with virtually impermeable films rather than implementing mitigation measures on the current application methods.

Response

The PMRA encourages the development of alternative application methods for soil fumigants aimed at reducing exposure to users, bystanders and the environment. However, considering the inherent toxicity and irritant properties of products containing chloropicrin, dazomet, metam sodium and metam potassium, and the potential for direct and indirect exposure from the current application methods, the PMRA believes that label improvements are warranted to further protect human health and the environment.

3.2.6 Recently developed application methods

The proposed mitigation measures should accurately reflect the recently developed application equipment currently used in Canada.

Response

The label improvements required by the PMRA encompass all application methods currently registered in Canada, including recently developed application equipment.

3.2.7 Plastic mulch films

In the context of the proposed mitigation measures, would plastic mulch films be considered a tarp?

Response

In the context of the label improvements required for the soil fumigant cluster, soil fumigation followed by the installation of any tarp, including plastic mulch films, are considered tarped applications. It is noted that only tarps listed on the USEPA Tarp Credit website (www.tarpcredits.epa.gov) qualify for buffer zone reduction credits.

3.3 Comment on the proposed Environmental Hazards label statements

The weight of evidence supports the conclusion that the use of chloropicrin as a soil fumigant does not pose a threat to ground or surface waters. Environmental Hazards label statements should not be required. A review of ground water monitoring data for chloropicrin from the United States was provided along with the comment.

Response

The PMRA's re-evaluation of the soil fumigant cluster is ongoing. As a first step in the re-evaluation of the soil fumigants, the PMRA is requiring the implementation of risk-reduction measures, including Environmental hazards statements, to further protect human health and the environment. The proposed Environmental Hazards label statements provide information as to the potential environmental hazards that may result from the use of the products, as well as precautions that should be followed to reduce runoff of the product into surface water. The proposed label improvements are consistent with measures adopted by the United States Environmental Protection Agency. Soil fumigants (or their major degradates) have been identified as having a potential to leach into ground and surface water by the USEPA based on their high solubility in water and low adsorption to soil.

3.4 Comments on the Personal Protective Equipment

3.4.1 Risk from fumigant being trapped against skin

For chloropicrin, chemical-resistant personal protective equipment (PPE) should not be worn because the fumigant can get trapped against the skin. It is recommended that only loose fitting clothing be worn. Chemical-resistant PPE should be worn only when handling liquid concentrate.

Response

To further protect handlers in Canada, chemical-resistant PPE is required for handlers performing tasks where there is a potential for contact with liquid fumigants. For liquid soil fumigant products, a long-sleeved shirt and long pants are required for handlers performing tasks where there is no potential for contact with the liquid fumigant.

3.4.2 Use of respirators

The proposed measures outline requirements for respiratory protection. The use of a respirator is not recommended as this would mask early warning properties in the event of a leak or problem with the application system.

Response

Specific respiratory protection and stop work trigger instructions, based on the USEPA REDs, are required on product labels. The early warning properties of chloropicrin and methyl isothiocyanate (MITC) (the primary degradate of dazomet, metam sodium and metam potassium in the environment) have been considered when establishing the triggers for wearing an air purifying respirator. For example, if at any time any handler experiences sensory irritation, either an air-purifying respirator must be worn by all handlers who remain in the application block or buffer zone (to protect workers from more severe irritation and respiratory effects), or operations must cease and handlers not wearing a respirator must leave the application block and buffer zone. Handlers can remove the respirator or resume operations when air monitoring shows that levels of chloropicrin or MITC have decreased below a set concentration. The requirement to wear a respirator when workers experience sensory irritations, and until air concentrations have decreased to an acceptable level, is considered necessary in order to protect workers from more severe irritation and respiratory effects which may occur as a result of exposure to these products.

3.4.3 Self contained breathing apparatus (SCBA)

The requirement for a self contained breathing apparatus (SCBA) to be on site is unwarranted for outdoor field application of soil fumigants. Canadian growers will not be able to justify costs associated with purchase, maintenance and training for this equipment. Only highly trained individuals (for example, firemen, rescue personnel, etc.) should have access to a SCBA.

Response

While the proposed SCBA was based on the USEPA RED for chloropicrin, the USEPA has since reconsidered this requirement, based largely on the considerations and concerns raised in the above-noted comment. Therefore, in consideration of the concerns raised during consultation, a SCBA is no longer required to be on site and ready for use in case of an emergency. Respiratory protection and stop work trigger instructions are required on the label of end-use products containing chloropicrin, dazomet, metam sodium and metam potassium. In addition, a fumigation management plan (FMP), including an emergency response plan, is required for all soil fumigant applications. These measures are considered adequate to address potential risks to handlers from inhalation exposure in case of an emergency.

3.5 Comment on the Fumigant Air Monitoring

The requirement for fumigant air monitoring is unwarranted. Canadian growers will not be able to justify costs associated with purchase, maintenance and training for this equipment.

Response

Based on the label improvements required by the PMRA, monitoring of fumigant air concentrations inside of the application block or buffer zone will first rely on sensory detection, since chloropicrin, dazomet, metam sodium and metam potassium have early warning properties. However, the collection of air monitoring samples is required if any handler experiences sensory irritation (for example, tearing, burning of the eyes or nose) in order to ensure that appropriate measures can be taken to protect handlers (for example, evacuation of the site) if required.

3.6 Comment on the Entry Restricted Period

The wording for the entry restricted period is unclear and should be revised.

Response

The label amendments required by the PMRA were revised to clarify the Entry Restricted Period.

3.7 Comments on Notification Requirements

3.7.1 Federal/provincial/territorial notification

The proposed minimum requirements for the fumigation management plan include federal/provincial/territorial and local notification. Additional information should be provided outlining the nature of the information to be provided and to which authority the information should be provided.

Response

Notification requirements to federal/provincial/territorial and local authorities have been removed from the fumigation management plan. The requirement that a copy of the Fumigation Management Plan and related documentation, including monitoring records, be maintained for a minimum of 2 years is still required.

3.7.2 Notification Responsibility

Where written documentation from the owner/operator of adjacent areas is required, or where posting is required, this should be the responsibility of the land owner not the supervising fumigant handler.

Response

The label amendments have been revised to remove the responsibility from the applicator for obtaining written agreements from owners/operators of adjacent areas and for posting signs. However, it remains the responsibility of the applicator to verify the site-specific Fumigation Management Plan to ensure that these activities have been carried out and documented. In addition, while Fumigant Application and Buffer zone signs may be posted by the land owner/operator prior to the start of the application, handlers remain responsible for removing signs following fumigation to ensure protection of workers and bystanders.

3.7.3 Posting requirements

Posting of signs should only be required at the edge of the buffer zone not both the edge of the buffer zone and the edge of the application block inside the buffer zone.

Response

Posting is required both at the edge of the application block and at the edge of the buffer zone. Distinct posting is required for these two areas because the restricted-entry periods can differ between the areas, and the Fumigant Application and the Buffer Zone signs contain different information.

3.7.4 Posting wording

It is recommended that the PMRA adopt the same wording for signs as was required by the USEPA.

Response

The requirements for the signs have been revised and are consistent with the USEPA requirements where appropriate.

3.8 Comments on the Good Agricultural Practices

3.8.1 Tree replant applications

REV2010-12, *Chloropicrin*, includes good agricultural practices for tree replant applications; however, tree replant is not a registered use in Canada for chloropicrin.

Response

The good agricultural practices label amendments for chloropicrin were revised and no longer include requirements pertaining to tree replant applications.

3.8.2 Field trash management

The proposed good agricultural practice requiring that trash pulled by the shanks to the end of the field be covered by tarp or soil before making the turn for the next pass is not realistic. This practice would result in an extra cost for the land owner since an additional handler will need to be on site with the appropriate equipment to cover the trash, or would require the land owner to be certified so he can be allowed to perform this task. Currently, trash pulled by the fumigation equipment is left temporarily at the field edge until the fumigation is complete. Then a few passes are made circumferentially to cover the rough areas created by lifting the equipment at the field ends. This operation covers the remaining trash as well as can reasonably be expected.

Response

The PMRA is requiring that trash pulled by the shanks to the end of the field be covered by tarp or soil to limit the natural chimneys that occur in the soil when crop residue is present. These “chimneys” allow the soil fumigants to move through the soil quickly and escape into the atmosphere. This may create potentially harmful conditions for workers and bystanders; therefore, trash pulled for the shanks to the end of the field must be covered in a timely manner. Based on the considerations and concerns raised in the above-noted comment, the PMRA is requiring that trash pulled by the shanks be covered following application.

3.8.3 Identifying unfavourable weather conditions

Identifying unfavourable weather conditions applies to all pesticide applications. This good agricultural practice should be part of the pesticide applicator certification training, but not required on product labels. Information should be provided as to where applicators can find out if a temperature inversion is forecast.

Response

Determining if unfavourable weather conditions exist or are predicted prior to the application is particularly important when using soil fumigants. These conditions may block the upward movement of air, resulting in the fumigant vapours being trapped near the ground and moving off-site in unpredictable directions. Consequently, identifying unfavourable weather conditions, including temperature inversions, is required as part of the mandatory good agricultural practices for soil fumigants. Local weather forecasts can be obtained, for example, on the Weather Office website of Environment Canada at www.weatheroffice.gc.ca/.

3.9. Comments on the Buffer Zones

3.9.1 Size of buffer zones

The proposed buffer zone distances are too large. Growers will not be able to accommodate distances. As a result, growers will not be able to use the soil fumigants or large areas of the field will be left untreated in order to avoid residential areas and roadways. In many cases, lack of alternatives will force switching to lower value crops.

Response

The PMRA acknowledges that depending on the parameters of the fumigation [for example, application rate, application block size, application method, product (active ingredient) used], the buffer zone distances can be large and may, in some cases, pose challenges to Canadian growers. However, the PMRA feels the distances are required to protect bystanders.

The buffer zones are consistent with those implemented for soil fumigant products in the United States. Since the publication of the PMRA proposed mitigation measures, the USEPA has reviewed additional data which has resulted in reduced buffer zones for chloropicrin, metam sodium, and metam potassium. These changes have been considered in the current (interim) decision and have resulted in the reduction of some buffer zone distances.

Where possible, the label improvements required by the PMRA include flexibility to enable growers to reduce as much as possible the required buffer zone distances [for example, available buffer zone credits, application method (for example, tarped versus untarped application), amount and/or type of product (active ingredient) used].

3.9.2 Buffer zone calculations

Additional information should be included in the decision document explaining how the buffer zone distances were calculated by the PMRA.

Response

The soil fumigant buffer zones required by the PMRA are based on buffer zones distances calculated by the USEPA. The USEPA buffer zones are based on empirical modeling [i.e. Probabilistic Exposure and Risk model for FUMigants (PERFUM)] which utilizes field volatility studies and meteorological data to determine the distance downwind from a fumigation site at which an acceptable air concentration is achieved. The USEPA considered field volatility from multiple locations in the United States (i.e. California, Florida, Washington and Michigan). Overall, the Canadian use pattern is encompassed by the assumptions used in the USEPA buffer zone calculations, and conditions observed in the U.S. field volatility studies (for example, soil moisture, soil temperature, etc.) are expected to conservative to the conditions that can be observed in Canada during

the spring season. On this basis, the PMRA determined that the USEPA buffer zones are applicable to the Canadian situation. For more information on how the USEPA buffer zones were calculated refer to the 2009 Amended Registration Eligibility Decisions (REDs) for chloropicrin, dazomet, metam sodium/potassium available at www.regulations.gov.

3.9.3 Limits on buffer zone size

Clarifications are required as to why application is prohibited when the buffer zone distance exceeds 800 meters, and why the minimum buffer zone distance is 10 meters when buffer zone credits could reduce the buffer zone further.

Response

The PMRA believes that buffer zones that exceed 800 meters become impractical to implement and difficult to enforce. The minimum buffer zone distance that will be required in Canada is 8 meters. Although in certain circumstances, with implementation of buffer zone credits, buffer zones can be reduced to less than 8 meters, the PMRA believes that maintaining a buffer zone of at least 8 meters is a good agricultural practice to protect bystanders. The limits to the maximum and minimum size of a buffer zone are consistent with limitations in place in the United States.

3.9.4 Buffer zone units

The application rates described in the buffer zone tables should be expressed in terms of the amount of product instead of the amount of active ingredient.

Response

The distances described in the buffer zone look-up tables are meant to apply to all the relevant products for a given active ingredient, and therefore are expressed in terms of the amount of active ingredient applied. The application rates outlined in the look-up tables that will be added to product labels are required to be expressed in terms of amount of product.

3.9.5 Overlapping adjacent buffer zones

The proposed requirement that buffer zones from adjacent fumigation blocks may not overlap unless 12 hours have passed will be difficult for Canadian growers because of the shorter seasonal window for soil fumigation in Canada.

Response

The PMRA recognizes that the prohibition of overlapping buffer zones from adjacent application blocks unless 12 hours have passed may pose challenges to Canadian growers because of the short seasonal window for soil fumigation in Canada. However, the PMRA feels this restriction is required to protect bystanders and to reduce the potential for off-site movement of chloropicrin or MITC from multiple fumigated fields.

3.9.6 Buffer zones extending into areas not under control of the owner/operator

The proposed requirements for buffer zones extending into areas not under the control of the owner/operator, including roadways, will not be feasible for Canadian growers. As a result, growers will be forced to take land out of production, or leave land untreated, to accommodate buffer zones within the areas under their control.

Response

For the protection of bystanders, buffer zones must not include residential areas, publically owned/operated areas, public or private roadways and rights of way, or agricultural areas not under the control of the owner/operator unless the area is not occupied and entry by non-handlers is prohibited (except for transit) during the buffer zone period. Transit (i.e. vehicular and bicycle traffic) on public or private roadways through the buffer zone is permitted.

When necessary, growers can obtain written agreement prior to the start of the application that buffer zones will be vacated during the Buffer Zone Period. The label improvements required by the PMRA also provide flexibility to enable growers to reduce as much as possible the required buffer zone distances [for example, available buffer zone credits, application method (for example, tarped versus untarped application), product (active ingredient) used].

3.9.7 Roadways

The proposed requirements are unclear if buffer zones can include roadways.

Response

Buffer zones can include public or private roadways and rights of way if the area is not occupied during the Buffer Zone Period and entry by non-handlers is prohibited during the this period, except for transit (i.e. vehicular and bicycle traffic) through the buffer zone.

3.9.8 Buffer Zone Period

It is unreasonable to expect growers to have their neighbours vacate their homes for the 5-day Buffer Zone Period. Growers will need guidance and options in the event that a neighbour refuses to vacate their home.

Response

For the protection of bystanders, buffer zones must not include residences unless they are not occupied during the buffer zone period. When necessary, growers will need to obtain written agreement prior to the start of the application that buffer zones will be vacated during the Buffer Zone Period. However, the label improvements required by the PMRA provide flexibility and ways to reduce the required buffer zone distances [for example, available buffer zone credits, application method (for example, tarped versus untarped application), amount and/or type of product (active ingredient) used] to enable growers to limit as much as possible the areas that must be vacated.

3.9.9 Availability of buffer zone credits to Canadian growers

The proposed buffer zone credits describe products and application equipment that are not available to Canadian growers.

Response

The buffer zone credits has been revised to better reflect typical soil fumigation use practices and products available in Canada.

3.9.10 Buffer zone credit for soil temperature

The 10% buffer zone credit allocated when soil temperature is less than 10ºC at a depth of 8 cm should be revised to 15ºC because the soil injection depth is deeper than 8 cm.

Response

The 10% buffer zone credit allocated when soil temperature less is than 10ºC was revised to indicated that temperature measurements must be recorded at the application depth or at a soil depth of 30 cm, whichever is shallower.

3.9.11 Buffer zone credits based on application methods

The PMRA should provide clarification on the reasons for differences in available buffer zone credits for the different application methods of metam sodium and metam potassium.

Response

The proposed buffer zone credits for metam sodium and metam potassium were revised to reflect revisions made to the buffer zone credits available for products containing these active ingredients in the United States. The same buffer zone credits are now available for all the application methods for these active ingredients.

3.10 Comments on Emergency Preparedness and Response

3.10.1 Conditions that require emergency preparedness and response plan

Response information for neighbours should only be required for residences and businesses that are within the buffer zone.

Response

If the buffer zone distance is larger than 8 meters and residences or businesses are located within 15 to 90 meters from the outer edge of the buffer zone, fumigation site monitoring must be conducted, or response information must be provided to neighbouring sites. This requirement will help ensure that if a problem occurs during or after the fumigation, it will be recognized quickly so that appropriate measures can be taken to reduce the risks of bystander exposure.

3.10.2 Response information for neighbours

Requirement to provide response information to neighbours could result in false reports of exposures.

Response

If the buffer zone distance is larger than 8 meters and residences or businesses are located within 15 to 90 meters from the outer edge of the buffer zone, fumigation site monitoring must be conducted, or response information must be provided to neighbouring sites. This requirement will help ensure that if a problem occurs during or after the fumigation, it will be recognized quickly so that appropriate measures can be taken to reduce the risks of bystander exposure.

3.10.3 Fumigation site monitoring

Weather conditions and worker schedules should be considered when establishing required timing for fumigation site monitoring.

Response

Fumigation site monitoring ensures that early action can be taken if unforeseen problems develop. As such, monitoring is required to be conducted at regular intervals through the buffer zone period, including during the day, during the night and during times when there is a greater chance that fumigant air concentrations may be higher and have the potential to move beyond the buffer zones. These periods include sunrise and sunset when winds are often calm and favour stagnant, inversion-like conditions.

3.10.4 Cost of fumigation site monitoring

Requiring that an applicator be on site after the application is complete to monitor air concentrations will be expensive for growers.

Response

If the buffer zone distance is larger than 8 meters and residences or businesses are located within 15 to 90 meters from the outer edge of the buffer zone, fumigation site monitoring must be conducted, or response information must be provided to neighbouring sites. This requirement will help ensure that if a problem occurs during or after the fumigation, it will be recognized quickly so that appropriate measures can be taken to reduce the risks of bystander exposure. The PMRA recognizes that the option of site monitoring may result in an increase in fumigation costs for growers. Alternatively, response information for neighbours can be provided.

3.11 Comment on the Fumigation Management Plan

The information proposed to be included in the fumigation management plan is too complex and detailed.

Response

The fumigation management plan requirements outlined in the proposal were intended to serve as a guide to be used by registrants to develop a Fumigation Management Plan guidance document that would be distributed as part of an applicator's manual. The requirements were based on existing fumigation management plans for the soil fumigant methyl bromide used in the United States. Since publication of the proposed mitigation measures, the USEPA has developed chemical-specific fumigation management plans for soil fumigant products.

The PMRA received numerous comments and recommendations related to the fumigation management plans. In an effort to improve usability and compliance, chemical-specific fumigation management plan templates will be developed by the PMRA in consultation with registrants and provincial regulatory agencies. Specific instructions for the preparation of a Fumigation Management Plan are also required to be part of the product label.